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Commissioner for Patents
PO Box 1450
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Re: U.S. Utility Patent Application
Application No. 09/721,508; Filed: November 22, 2000
For: **High Throughput Screening Assay Systems in Microscale Fluidic Devices**
Inventors: Parce *et al.*
Our Ref: 2052.0020006/LEA/EDH

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply Brief Under 37 C.F.R. § 1.193(b)(1); and

2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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LEA/EDH:nar
Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 5229
Parce *et al.*	Art Unit: 1639
Appl. No. 09/721,508	Examiner: Tran, My Chau T.
Filed: November 22, 2000	Atty. Docket: 2052.0020006/LEA/EDH
For: **High Throughput Screening Assay Systems in Microscale Fluidic Devices**	

Reply Brief Under 37 C.F.R. § 1.193(b)(1)

Mail Stop Appeal Brief - Patents

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants filed a Brief on Appeal ("Appeal Brief") to the Board of Patent Appeals and Interferences for the above-captioned application on October 14, 2003. The appeal is directed to the final rejection of claims 78, 81 and 87 under 35 U.S.C. § 112, first paragraph, as set forth in the Office Action mailed February 12, 2003 (Paper No. 18). The Examiner's Answer ("Answer") was mailed December 17, 2003. In reply to the Answer, Appellants submit this Reply Brief ("Reply") under 37 C.F.R. § 1.193(b)(1).

I. Related Appeals and Interferences

It was noted in the Appeal Brief that Appellants' undersigned representative was not aware of any appeals or interferences related to this application. *See* Appeal Brief at page 1. In the Answer, the Examiner correctly noted that claims 78, 81 and 87 were copied from U.S. Patent No. 6,103,199 by Appellants in an effort to provoke an interference. *See* Answer at 2.

However, at the time of filing the Appeal Brief and also as of the filing of this Reply, no interference is known by Appellants to have been declared.

II. Grouping of the Claims

In the Appeal Brief, Appellants stated that claims 78, 81 and 87 should be treated as one group and should stand or fall together. Appeal Brief at 4. The Examiner incorrectly stated Appellants' position in the Answer. The Examiner stated that Appellants' brief includes a statement that claims 78, 81 and 87 do not stand or fall together. Answer at 3. The Examiner's statement should state that Appellants' brief includes a statement that claims 78, 81 and 87 do stand or fall together.

III. Discussion

A. 35 U.S.C. First Paragraph "Written Description" Requirement

In the Answer, the Examiner stated that the Appellants addressed the final rejection set forth in the February 12, 2003 Office Action as a "lack of written description" rejection. Answer at 5. The Examiner asserts in the Answer that the rejection set forth in the February 12, 2003 Office Action was a "new matter" rejection. Answer at 5. Appellants disagree with the Examiner's characterization of the prior rejection.

The final rejection of claims 78, 81 and 87 set forth in the February 12, 2003 Office Action was under 35 U.S.C. § 112, first paragraph. Paper No. 18 at 3. The language of this statute states, "The specification shall contain a *written description* of the invention, and of the manner and process of making and using it . . ." (emphasis added). Formal "new matter" rejections are based on 35 U.S.C. § 132. The language of this statute states, ". . . No amendment shall introduce *new matter* into the disclosure of the invention" (emphasis added). 35 U.S.C. § 132. Accordingly, Appellants were correct to address the final rejection set forth in the February

12, 2003 Office Action as a "lack of written description" rejection because the rejection was made under 35 U.S.C. § 112, first paragraph.

B. Adequate Support in the Specification for the Claimed Subject Matter

Appellants set forth in the Appeal Brief that the present specification describes microfluidic devices that are useful in screening large numbers of different compounds, and notes that screening assays have typically been set up in multi-well reaction plate formats, e.g., multi-well microplates. *See* Appeal Brief, page 7, lines 17-20 (citing Specification, page 7, lines 5-9) and lines 20-23 (citing Specification, page 10, lines 29-32). Appellants also cited numerous issued patents disclosing the well-plate formats specified in claims 78, 81 and 87 to show that those well-plate formats were well known in the art as of the effective filing date of the application. *See* Appeal Brief, page 8, line 17 to page 9, line 14. Then, Appellants applied the Federal Circuit's written description requirement to the present application. Based on the Federal Circuit's written description standard, the support disclosed in the specification, and what was well known in the art at the time of the invention, a person of ordinary skill in the art would recognize that the Appellants clearly demonstrated possession of the subject matter of claims 78, 81 and 87. Therefore, claims 78, 81 and 87 meet the written description requirement set forth by the Federal Circuit.

C. Examiner's Argument

The Examiner agreed in the Answer that "the term 'multi-well' microplate embraces a multitude of different formats of sample wells." *See* Examiner's Answer, page 5, lines 10 and 11. Additionally, the Examiner stated that "the term 'multi-well' microplates includes several different formats of sample wells." *See* Examiner's Answer, page 6, lines 16 and 17. The Examiner stated, however, that although the Appellants' specification embraces a multitude of

different formats and includes several different formats of sample wells, the specification does not provide specific support for the particularly claimed embodiments that use microplates with the 96, 192, 384, or 1536 sample well formats and that "one of ordinary skill in the art would not envision that the term 'multi-well' microplates would be specifically for sample well formats of a 96, 192, 384 or 1536 well plate." Answer at 6 (emphasis in original).

D. Examiner's Argument is Not Supported by the Law

As noted in the Appeal Brief, the written description requirement does not require that the Appellants describe exactly what is claimed. *See* Appeal Brief, page 5, lines 10-13 (citing *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000)). Instead, the description must allow persons of ordinary skill in the art to recognize that the Appellants were in possession of the subject matter of the claims. *See* id. Claimed subject matter that is well known in the art need not be described in specific detail in the specification. *See* Appeal Brief, page 6, lines 3-6 (citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986)). At the time of the invention, microplates with 96, 192, 384 and 1536 sample well formats were well known in the art. See Appeal Brief, page 8, line 17 to page 9, line 14. Accordingly, one skilled in the art would recognize that the term "microplates" encompassed microplates with those well-known formats. According to the written description requirement set forth by the Federal Circuit, Appellants are not required to describe well-known microplate formats in the specification in order to claim embodiments using those formats. Accordingly, the Examiner's analysis supporting the rejection of claims 78, 81 and 87 is not correct.

IV. Conclusion

In light of the arguments above, as well as those set forth in the Appeal Brief, Appellants respectfully submit that the final rejections of claims 78, 81 and 87 under 35 U.S.C. § 112, first paragraph, are improper and should be reversed.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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